DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New Orleans District
6600 Plaza Drive, Suite 400
New Orleans, LA 70127

June 5, 2002

VIA FEDERAL EXPRESS

Mr. George A. Drakos, President
Fresh Fish, Inc.
1116 2nd Avenue North
Birmingham, AL 35203

Warning Letter No. 02-NSV-26

Dear Mr. Drakos:

On April 2 – 4, 2002, the Food and Drug Administration (FDA) conducted an inspection of your firm located at 1116 2nd Avenue North, Birmingham, AL. The inspection revealed that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123) and the Food Labeling regulations (21 CFR Part 101). Seafood HACCP and food labeling information is also available through links in FDA's home page at www.fda.gov.

These deviations, most of which were previously brought to your attention in our letter dated April 20, 1998 and during an inspection conducted September 19, 1999 cause your firm to be in violation of sections 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act) because your seafood products have been prepared, packed, or held under insanitary conditions whereby they may have become contaminated with filth or rendered injurious to health.

The deviations are as follows:

- Your "all-inclusive" HACCP plan does not comply with **21 CFR 123.6(b)(2)**. You chose to group different kinds of fish and fishery products together in one plan. However, your "all-inclusive" HACCP plan attempts to group products that have different hazards e.g. pathogens, histamine, ciguatera toxin, sulfites and metals etc. Separate HACCP plans must be prepared when the food safety hazards, critical control points, critical limits, monitoring, verification and record keeping procedures are not identical.

- Your "all-inclusive" HACCP plan does not establish the critical control points, critical limits, monitoring, verification and record keeping procedures that are specific for each food safety hazard. **[21 CFR 123.6(c)(1), (2), (3), (4), (6), and (7)]**

- Failure of the most responsible individual to sign and date the HACCP plan to signify that it has been accepted for implementation. **[21 CFR 123.6(d)]**

- Failure to reassess the HACCP plan at least annually. **[21 CFR 123.8(a)(1)]**

- Failure to maintain adequate monitoring records including all mandatory descriptive information. **[21 CFR 123.9(a)]**

- Receiving logs do not include a reviewer's signature and date. **[21 CFR 123.8(a)(3)]**

- Failure to calibrate thermometers and temperature recording devices as required by **21 CFR 123.8(a)(2)**.

- Failure to adequately monitor and document sanitation conditions, practices and corrections during processing. **[21 CFR 123.11(b) & (c)]**

- Insanitary conditions and poor employee practices that could result in contamination of finished product. **[21 CFR 110]**

Furthermore, your firm is vacuum packaging refrigerated seafood products using [redacted] millimeter and [redacted] millimeter, low-density polyethylene bags. *Clostridium botulinum* is a hazard in vacuum packaged seafood products, unless the oxygen permeability rate is at least 10,000 cc/m^2/24 hours. The addendum to your HACCP plan indicates that you are using a [redacted] millimeter low density polyethylene has an oxygen permeability rate of [redacted] However, your firm could not provide any documentation to show that [redacted] meets or exceeds the oxygen permeability rate of 10,000 cc/m^2/24 hours requirement listed in the Fish & Fisheries Products Hazards & Controls Guidance: *Third Edition*.

It is your firm's responsibility to have documentation that the oxygen permeability rate [redacted] meets or exceeds the oxygen permeability rate of 10,000 cc/m^2/24 hours. Otherwise, a HACCP plan with critical control points, critical limits, monitoring, verification and record keeping procedures that are specific for *Clostridium botulinum* would be required for your vacuum packaged refrigerated seafood products.

In addition, the "CLASSIC SHRIMP HEADLESS" and the "CLASSIC SHRIMP PEELED" repackaged by your firm are misbranded within the meaning of Section 403(i)(2) of the Act, in that your box label fails to bear a statement of ingredients as required by **21 CFR 101.4(a)(1)**.

This letter may not list all the deviations at your firm. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Current Good Manufacturing Practice regulations (21 CFR 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug and Cosmetic Act and all applicable regulations.

You should take prompt action to correct these violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice. These actions include, but are not limited to, seizure and/or injunction.

Please respond in writing within fifteen (15) working days from the receipt of this letter. Your response should outline the specific steps you have taken to correct the above deficiencies. Your reply should be addressed to the attention of Karen Gale Sego, Compliance Officer, Food and Drug Administration, 297 Plus Park Boulevard, Nashville, TN 37217.

Sincerely,

Carl E. Draper

Carl E. Draper
Director, New Orleans District

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